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records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least 1 year after the expiration of the shelf life of the infant formula.

[54 FR 4008, Jan. 27, 1989, as amended at 67 FR 9585, Mar. 4, 2002]

PART 108—EMERGENCY PERMIT CONTROL

Subpart A—General Provisions

Subpart B—Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit

AUTHORITY: 21 U.S.C. 342, 344, 371.

SOURCE: 42 FR 14334, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 108.3 Definitions.

(a) The definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part.

(b) *Commissioner* means the Commissioner of Food and Drugs.

(c) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended.

(d) *Permit* means an emergency permit issued by the Commissioner pursuant to section 404 of the act for such temporary period of time as may be necessary to protect the public health.

(e) *Manufacture, processing, or packing of food in any locality* means activities conducted in a single plant or establishment, a series of plants under a single management, or all plants in an industry or region, by a manufacturer, processor, or packer.

§ 108.5 Determination of the need for a permit.

(a) Whenever the Commissioner determines after investigation that a manufacturer, processor, or packer of a food for which a regulation has been promulgated in subpart B of this part does not meet the mandatory conditions and requirements established in such regulation, he shall issue to such manufacturer, processor, or packer an order determining that a permit shall be required before the food may be introduced or delivered for introduction into interstate commerce by that person. The order shall specify the mandatory conditions and requirements with which there is a lack of compliance.

(1) The manufacturer, processor, or packer shall have 3 working days after receipt of such order within which to file objections. Such objections may be filed by telegram, telex, or any other mode of written communication addressed to the Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–605), 5100 Paint Branch Pkwy., College Park, MD 20740. If such objections are filed, the determination is stayed pending a hearing to be held within 5 working days after the filing of objections on the issues involved unless the Commissioner determines that the objections raise no genuine and substantial issue of fact to justify a hearing.

(2) If the Commissioner finds that there is an imminent hazard to health, the order shall contain this finding and the reasons therefor, and shall state that the determination of the need for a permit is effective immediately pending an expedited hearing.

(b) A hearing under this section shall be conducted by the Commissioner or his designee at a location agreed upon by the objector and the Commissioner or, if such agreement cannot be reached, at a location designated by the Commissioner. The manufacturer, processor, or packer shall have the right to cross-examine the Food and